

In the United States Court of Federal Claims

No. 16-997V

(Filed Under Seal: September 17, 2020)
(Reissued: October 5, 2020)¹

**ANNA PEREKOTIY, on behalf of her
minor child, S.K.,**

Petitioner,

v.

* Vaccine case; Motion for Review
* Diphtheria, Tetanus, Cellular Pertussis (DTaP)
* Hepatitis B Inactivated Polio (IPV) Vaccines;
* atopic eczema dermatitis; *Althen* prongs;
* *Loving* prongs, Motion for Review denied

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**SECRETARY OF HEALTH AND
HUMAN SERVICES,**

Respondent.

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Andrew Donald Downing, Phoenix Arizona, for Petitioner.

Zoe Wade, Julia Marter Collison, and Lynn Elizabeth Ricciardella, United States Department of Justice, Washington, DC, for Respondent.

OPINION AND ORDER

DAMICH, Senior Judge

On May 20, 2020, Petitioner filed, on behalf of her daughter, S.K., a petition for review of the Chief Special Master's Decision denying compensation under the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2018) ("Vaccine Act"). Petitioner had alleged that the S.K.'s exposure to the Hepatitis B vaccine on August 21, 2013, caused her to develop atopic dermatitis, and that the subsequent vaccinations for Diphtheria, Tetanus, acellular Pertussis ("DTaP") and inactivated polio ("IPV") administered on September 18, 2013, significantly aggravated her skin condition. On April 20, 2020, Chief Special Master Brian H. Corcoran denied compensation on grounds that Petitioner had not preponderantly established that the Hepatitis B vaccine caused the initial onset of S.K.'s atopic dermatitis, or that the DTaP

¹ Vaccine Rule 18(b), included in Appendix B of the Rules of the United States Court of Federal Claims, affords each party fourteen days in which to object to the disclosure of (1) trade secrets or commercial or financial information that is privileged or confidential or (2) medical information that would constitute "a clearly unwarranted invasion of privacy." Neither party objected to the public disclosure of any information contained in this opinion.

and IPV vaccines S.K. received a month later significantly aggravated her then-existing dermatologic condition.

In her motion for review, Petitioner requests this Court to enter judgment in her favor arguing that the Chief Special Master improperly weighed the evidence and misapplied the relevant legal standards. For the reasons set forth below, the Court finds that the Chief Special Master's factual findings are supported by substantial evidence and that he correctly applied the relevant legal standards. Petitioner's motion for review is, therefore, denied.

I. Background

A. Factual Background

S.K. was born healthy on July 16, 2013.² At the time of her birth, she received her first dose of the Hepatitis B vaccine. There was no reported adverse reaction. On July 22, 2013, S.K. was seen by Dr. Jennifer Cropp, M.D., for a newborn baby visit. At that visit, the doctor did not note any abnormalities. At her two-week exam, S.K. exhibited drainage from her right eye. S.K. also presented redness in her left armpit, which Dr. Cropp attributed to moisture. Dr. Cropp instructed Petitioner to keep the area clean and dry.

S.K received her second dose of Hepatitis B vaccine on August 21, 2013, by Dr. Matthew Barcellona, M.D., of North Scottsdale Pediatric Associates, during a one-month well-baby check. At that time no abnormalities or dermatological concerns and no adverse reactions to the vaccine were noted in the doctor's notes.

Approximately one month later, on September 16, 2013, S.K. was seen by Dr. Colin Petranu, M.D., of North Scottsdale Pediatric Associates, complaining of redness and rash that petitioner reported had developed three weeks prior (or approximately six days after receiving her second Hepatitis B vaccination) and had failed to improve. The doctor noted that S.K. exhibited flaky skin on her head, diagnosed as seborrhea,³ as well as red, raw, macerated neck folds without drainage or crusting, diagnosed as intertrigo.⁴ S.K. was prescribed a moisturizing cream and the doctor indicated that if it did not improve he would consider prescribing a steroid cream.

² The Court derives much of the background from the previous ruling in this case, *see generally Perekotiy v. Sec'y of HHS*, No. 16-997V, slip op. (Fed. Cl. Spec. Mstr. April 20, 2020).

³ Seborrhea is characterized by a dry, scaly dermatitis in areas of the body with sebum-producing glands, including the scalp, chest, back, axilla, and groin. *Dorland's Illustrated Medical Dictionary* 1657 (33d ed. 2020) (hereinafter "Dorland's").

⁴ Intertrigo is a superficial dermatitis caused by moisture, friction, warmth, and sweat retention that is characterized by erythema, maceration, burning, itching, and sometimes erosions, fissures, exudations, and secondary infections. *Dorland's* at 939.

Two days later, on September 18, 2013, S.K. was seen for her two-month well-baby visit. The examination showed that S.K. had rough patches on her body, scalp flakiness, and red macules in her neck folds. S.K. was again diagnosed with intertrigo, but her seborrhea diagnosis was changed to atopic eczema dermatitis.⁵ During this visit, S.K. received four vaccines: DTaP, Hib, IPV, and pneumococcal. Petitioner refused the rotavirus vaccine and signed a waiver to that effect.

On November 20, 2013, petitioner returned to Dr. Barcellona with S.K. Petitioner reported S.K. had a bad reaction to her shots causing leg redness. The skin exam revealed red and rough patches as well as scaly skin on her torso, scalp, and legs. Petitioner was not administering steroids which had previously been prescribed to treat S.K.'s skin condition, because petitioner felt steroids are "bad." Dr. Barcellona noted it was unclear whether the shot reaction was local, and her eczema was the bigger issue, or if the shot caused more reaction.

On December 9, 2013, S.K. was seen by a certified physician assistant, for evaluation of a persistent rash following her September 18, 2013, vaccinations. The record indicated that S.K. exhibited dry red patches on her scalp, face, abdomen, and both lower extremities. She was diagnosed with eczema.

At her six-month well-baby visit, on January 15, 2014, the records noted that S.K. had eczematous rash on both legs. The doctor then recommended that S.K. undergo formal evaluation with an allergist and pediatric dermatologist, and Petitioner was encouraged to continue to have S.K. vaccinated.

On January 22, 2014, S.K. saw Dr. Ronald Jorgensen, of the Arizona Asthma and Allergy Institute. A physical examination revealed a large dry patch on S.K.'s right leg and some dry skin on her arms and legs. Dr. Jorgensen recommended testing of vaccines prior to the administration of the vaccines. He suggested that S.K. take a skin prick and intradermal test of the DTaP vaccine. After the skin prick test, if it was found that those were tolerated, he suggested following up with a one-tenth dose, followed by the remainder of the dose. Dr. Jorgensen also suspected S.K. might be allergic to eggs, so he instructed petitioner to avoid eggs and egg-based vaccines and prescribed an Epi Pen Jr. as a precaution.

On January 29, 2014, Dr. Jorgensen gave S.K. a skin prick test of the DTaP vaccine. Following the test, S.K. exhibited a raised wheal of 3 x 4 mm, and an erythema flare 10 x 15 mm in size. Dr. Jorgensen interpreted these results as a positive allergic reaction to the DTaP vaccine and advised petitioner to avoid Diphtheria-Tetanus-containing vaccines in the future.

Then, on February 19, 2014, S.K. received a skin prick test of the IPV vaccine, again by Dr. Jorgensen. The skin prick test of the IPV vaccine showed no reaction. S.K. was then given an intramuscular injection with a one-tenth dose of IPV, which generated a wheal 3 x 3 mm in size, and an erythema flare 5 x 9 mm in size. Dr. Jorgensen concluded S.K. was likely allergic to

⁵ An atopic eczema dermatitis is an allergic pruritic dermatitis that is characterized by erythema, edema, inflammatory infiltrates in the dermis, crusting, and scaling. *Dorland's* at 171, 586.

both the DTaP and IPV vaccines and advised against receiving further vaccinations for at least six months.

S.K.’s nine-month well-baby visit was on April 24, 2014. The medical records showed that S.K.’s physical examination was negative for pruritis, rash, and skin lesions, and positive for atopic dermatitis and severe allergies to eggs, oats, and vaccines. At her twelve-month well-baby visit on July 29, 2014, the same findings were noted.

B. Procedural Background

Petitioner filed a petition for compensation under the Vaccine Act on August 12, 2016, alleging that S.K. experienced a severe adverse reaction (including some developmental sequelae) to several vaccines that she received on September 18, 2013. On July 17, 2017, Petitioner filed a second amended petition claiming that the S.K.’s exposure to the Hepatitis B vaccine on August 21, 2013, caused her to develop atopic dermatitis, and that the subsequent vaccinations for Diphtheria, Tetanus, acellular Pertussis (“DTaP”) and inactivated polio (“IPV”) administered on September 18, 2013, significantly aggravated her skin condition.

In support of her claims, Petitioner submitted expert reports from Dr. David Axelrod, a clinical immunologist, and Dr. Schield Wikas, a board-certified dermatologist. Petitioner also relied on the medical reports by S.K.’s treating dermatologist, Dr. Jorgensen. In response, Respondent submitted expert reports from Dr. Francis Lobo, a clinical immunologist, and Dr. Jonathan Spergel, a board-certified allergist and immunologist. Both parties also submitted various amounts of scientific and medical literature in support of their positions.

On March 18, 2019, Petitioner advised the Chief Special Master that she elected to move for a ruling on the record, rather than proceeding with a hearing. On May 16, 2019, Petitioner filed a motion for decision on the record. Respondent filed his responsive brief on July 11, 2019; Petitioner filed her reply on August 14, 2019. On April 20, 2020, the Chief Special Master issued his ruling on entitlement (“Dec.”).

After summarizing the cases’ factual and procedural history, the Chief Special Master provided an extensive description of the credentials, reports and the medical and scientific literature relied upon by the experts. He also set forth the legal standards for his review of the experts’ opinions, for his review of the medical and scientific literature, and for Petitioner to establish causation and significant aggravation.

There is no dispute in this case about the administration of the vaccines in question, S.K.’s diagnoses, or the date S.K. most likely experienced onset (around August 27, 2013). Thus, Petitioner’s claim regarding initiation of S.K.’s atopic dermatitis turned on whether the Hepatitis B vaccine could cause atopic dermatitis in the manner proposed, whether it did, and whether S.K.’s onset was within a medically acceptable timeframe. To answer these questions, the Chief Special Master first focused on the issue of causation analyzing the claim under the three prongs as set forth in *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). He then focused on Petitioner’s second claim—significant aggravation—analyzing that

claim to see if it met the required six prong test as set forth in *Loving v. Sec'y of Health & Human Servs.*, 86 Fed. Cl. 135 (2009).

In accordance with his analysis, the Chief Special Master concluded that petitioner had not preponderantly satisfied any of the *Althen* prongs for her first claim. In his analysis, the Chief Special Master held that the vaccine might be associated with atopic dermatitis. *Dec.* at 26. He further found that some of the literature filed in the case by Petitioner supported the conclusion that the vaccine could trigger the allergic reaction. *Id.* However, Respondent filed literature as well, to which the Chief Special Master weighed against Petitioner's literature. This analysis led to the finding that Respondent's literature failed to overcome Petitioner's showing. *Id.* at 27.

Not relying solely on the literature, the Chief Special Master then focused on a 2008 epidemiological study, Grüber, and its conclusion that the vaccination did not pose an increased risk for either the development or exacerbation of atopic dermatitis. *Id.* This study was not rebutted by Petitioner. *Id.* In the end, the Chief Special Master then concluded that taken together—both the Respondent's literature and the Grüber study—that evidence sufficiently rebutted Petitioner's evidence and therefore Petitioner did not satisfy *Althen* prong I. *Id.*

Similarly, the Chief Special Master found that Petitioner did not offer preponderant evidence to satisfy the second prong of *Althen*—requiring a logical sequence between cause and effect between the alleged injury and the vaccine received. *Id.* In particular he noted the following: that S.K. had received the Hepatitis B shot at birth and did not have any adverse reaction, that the second dose was administered and not until six days later did S.K. begin exhibiting dermatological symptoms which was not diagnosed until a month later as atopic dermatitis, and that no allergy testing was done for the Hepatitis B vaccine. *Id.* He therefore concluded that “there was insufficient evidence that S.K. was allergic to the Hepatitis B vaccine.” *Id.* For those reasons, the Chief Special Master found that the Petitioner had not satisfied her burden under *Althen* prong 2.

And finally, with regard to the third prong, the Chief Special Master found that even if Petitioner had satisfied *Althen* prongs 1 and 2, Petitioner's claims would fail under the third prong stating:

Respondent's experts, along with much of the literature submitted in this matter, proposed that the onset of delayed allergic reactions will occur *at least* within forty-eight hours of allergen exposure, peaking three to four days post-exposure. Chung at 51; Wood at 521–22. But the medical records in this case suggest that S.K. did not display symptoms of atopic dermatitis until August 27, 2013—six days post-vaccination. Ex. 7 at 15. Thus, the medical record establishing S.K.'s onset was inconsistent with the most scientifically reliable/medically acceptable timeframe

Id. at 27-28. (emphasis in the original). The Special Master did not credit Petitioner's argument for a longer timeframe as presented by her expert Dr. Axelrod. *Id.* at 28.

Thereafter, the Chief Special Master analyzed the remaining three factors under *Loving*. Again, the Chief Special Maser found that Petitioner had not satisfied any of those elements, either. First, he found that the Petitioner had not provided a reliable theory of causation. He analyzed the literature provided by Petitioner in his decision but found that the Grüber study was “especially difficult to overcome.” *Id.* at 29. Petitioner did not rebut this study, “an epidemiologic study that goes directly to [Petitioner’s] central contentions.” *Id.* He further noted that “a petitioner need not *offer* epidemiologic evidence to prevail,” *id.* (emphasis in the original), but that he could consider relevant studies that relate to a claim. *Id.* Epidemiologic studies, he noted, are “entitled to evidentiary weight.” *Id.* Therefore, relying on the study, the Chief Special Master concluded that:

Overall, Petitioner’s showing on this *Loving* element was not ultimately persuasive and was not aided by her expert showing. Respondent, on the other hand, offered credible and persuasive expert testimony that (coupled with the filed literature) substantially detracted from Petitioner’s proffered theory. Because of the foregoing, my weighing process did not produce a finding in Petitioner’s favor on the fourth *Loving* factor, despite the fact that Petitioner offered some reliable evidence. As science advances, and/or this issue is subject to further (or updated) study, more evidence may be developed that supports the kind of claim asserted herein. But it does not exist today. Under the legal standards I must apply, the evidence in this case does not support a finding that the DTaP and IPV vaccines can likely produce atopic dermatitis exacerbations.

Id. at 30.

Next, the Chief Special Master held that Petitioner was able to show that S.K.’s atopic dermatitis worsened after vaccination but that she did not prove that it worsened due to the vaccination. *Id.* at 30. First, relying again on the Grüber study, the Chief Special Master held:

... there is thin evidence suggesting that vaccines can cause or exacerbate atopic dermatitis generally. *See Grüber* at 1469. Petitioner’s overreliance on the temporal association between S.K.’s exacerbation and vaccination is insufficient to sustain her claim in the face of scientific and epidemiological evidence to the contrary. *See Moberly*, 592 F.3d at 1323–24.

Id. The Chief Special Master also reviewed the medical records finding that the record did not otherwise persuasively link the DTaP or IPV vaccines to S.K.’s worsening. The Chief Special Master reviewed the evidence presented by Petitioner. He then reviewed Drs. Lobo and Spergel expert reports finding that their reports raised reasonable points about the reliability of Dr. Jorgensen’s testing results. *Id.*

And finally, with regard to the final and sixth *Loving* factor, the Chief Special Master found that Petitioner had met her burden. *Id.* at 32. However, the Chief Special Master wrote:

But despite these findings, Petitioner has not provided sufficient evidence to carry her burden; especially when rebutted with the epidemiological evidence

offered by Respondent in this matter. Specifically, Petitioner's literature offered in support of her proposed theory, while appearing to be viable at first glance, was substantially outweighed by the Grüber epidemiological study, which found no causal connection between childhood vaccination and the development or exacerbation of atopic dermatitis. Similarly, Petitioner's experts failed to provide adequate support for the proposed theory. Though qualified to offer an opinion in the matter, Drs. Axelrod and Wikas were less credible overall in the opinions they offered when compared to Respondent's expert, Dr. Spergel. Thus, I find that Petitioner has failed to meet her overall burden under *Loving*.

In finding that Petitioner had not satisfied *Althen* or *Loving*, the Chief Special Master denied Petitioner's request for compensation.

Thereafter, Petitioner timely filed a motion for review on May 20, 2020 and Respondent filed a response on June 19, 2020. Petitioner then filed a motion to file a reply brief on June 26, 2020. Respondent did not object. Therefore, the Court **GRANTS** Petitioner's motion to file a reply brief. The case is now ripe for decision.

II. Discussion

A. Standard of Review

Under the Vaccine Act, a court may set aside a Special Master's findings of fact or conclusions of law only if they are found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 42 U.S.C. § 300aa-12(e)(2)(B). With respect to findings of fact, the special master has broad discretion to weigh expert evidence and make factual determinations. *See Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). "If the special master has considered the relevant evidence of the record, drawn plausible inferences and articulated a rational basis for the decision, reversible error will be extremely difficult to demonstrate." *Hines v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1528 (Fed. Cir. 1991). This Court ought not to second-guess the Special Master's fact-intensive conclusions, particularly in cases "in which the medical evidence of causation is in dispute." *Hodges v. Sec'y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993). In such cases, which often involve expert testimony, the Federal Circuit has "unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act." *Porter v. Sec'y of Health & Human Servs.*, 663 F.3d 1242, 1250 (Fed. Cir. 2011). "Such credibility determinations are 'virtually unreviewable'" on appeal. *Id.* at 1251. With respect to questions of law, legal rulings are reviewed *de novo* under the "not in accordance with law" standard. *See, e.g., Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Munn v. Sec'y of Health & Human Servs.*, 970 F.2d 863, 870 n.10 (Fed. Cir. 1992).

B. Legal Standards

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—

corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a “Non-Table Injury”). *See Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); see also Moberly*, 592 F.3d at 1321; *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006). In this case, Petitioner does not assert a Table claim; therefore, the claims are analyzed under the standard as set forth for a non-table injury.

“In off-Table cases . . . it is the petitioners’ burden to prove actual causation by a preponderance of the evidence.” *Boatmon v. Sec'y of Health & Human Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019) (citing *Moberly*, 592 F.3d at 1322). To establish entitlement to an award of compensation for a non-Table injury, a petitioner must show that the vaccine brought about the injury, by providing:

- (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen, 418 F.3d at 1278. Petitioner’s burden to show a proximate temporal relationship means “preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation.” *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). That is, the time between vaccination and onset of symptoms must be consistent with petitioner’s proposed theory of causation under *Althen* prong I. *Id.* at 1352.

When a petitioner alleges a significant aggravation of a pre-existing condition, she must satisfy each of the three *Althen* prongs, but must also adduce evidence establishing:

- (1) the person’s condition prior to administration of the vaccine, (2) the person’s current condition (or the condition following the vaccination if that is also pertinent), and (3) whether the person’s current condition [or condition following the vaccination] constitutes a ‘significant aggravation’ of the person’s condition prior to vaccination.

Loving, 86 Fed. Cl. at 144.

C. Petitioner’s Objections

When evaluating a motion for review, as stated above, it is the Court’s task to determine whether the Special Master, or in this case, the Chief Special Master, properly considered the relevant evidence in the record before him, came to factual conclusion based on plausible inferences, and provided a reasoned explanation for his conclusion and decision. *Hines*, 940 F.2d at 1528. It is not the Court’s task to second-guess the Special Master, especially in cases “in which the medical evidence of causation is in dispute.” *Hodges*, 9 F.3d at 961. Thus, on review, the Court accords deference to the Chief Special Master’s factual findings and fact-based conclusions.

Nevertheless, the majority of Petitioner's memorandum expresses general disagreement with the Chief Special Master's evaluation and weighing of the evidence. Specifically, Petitioner argues four points of error by the Chief Special Master. First, Petitioner alleges that the Chief Special Master should have afforded greater weight to S.K.'s treating dermatologist. Second Petitioner contends that the Chief Special Master should have found Petitioner's evidence on *Althen* prong I ultimately persuasive. Third, Petitioner argues that her expert witness's testimony, that six days from exposure to onset of symptoms, is a medically reasonable timeframe. Fourth, and final, Petitioner argues that Petitioner's evidence in support of her significant aggravation claim was persuasive under *Loving*.

In light of the Chief Special Master's detailed and reasoned decision, this Court concludes that none of these arguments provides a basis for this Court to set aside the Chief Special Master's Decision.

1. The Challenged Findings of Fact were Not Legal Error

In her first objection, Petitioner contends that the Chief Special Master committed legal error by giving insufficient deference to S.K.'s treating dermatologist. Specifically, Petitioner asserts that:

- The Chief Special Master minimized the multiple important pieces of evidence submitted by Dr. Jorgenson, the treating physician;
- The Chief Special Master erred by not giving Dr. Jorgenson credible deference for his opinions as he was S.K.'s treating physician and in the best position to determine the factual and medical issues surrounding vaccination and treatment, including onset of relevant symptoms and causation assignment citing *Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367 (Fed. Cir. 2009); *Zatuchni v. Sec'y of Health & Human Servs.*, 69 Fed. Cl. 612, 623 (2006);
- The Chief Special Master should have found that the testimony by Dr. Jorgenson that S.K. should not undergo further immunizations supported vaccine causation citing to *Kelley v. Sec'y of Health & Human Servs.*, 68 Fed. Cl. 84, 98, 100 (2005); *Andreu v. Sec'y of Health & Human Servs.*, No. 98-817V, 2008 WL 2009746 (Fed. Cl. Mar. 3, 2008).

A good portion of Petitioner's motion for review is her disagreement with the Chief Special Master's determination that Respondent's expert witness was more persuasive than S.K.'s treating dermatologist, Dr. Jorgenson.

Turning to the decision, the Chief Special Master discussed the medical records provided by Dr. Jorgenson by setting forth a summary of Dr. Jorgenson's allergy testing and treatment of S.K. and noted his conclusion that S.K. was likely allergic to both DTaP and IPV vaccines. Dec.

at 4-5. According to Petitioner, this should have resulted in the Chief Special Master finding her witness more persuasive.

However, the Chief Special Master then considered the contradictory expert reports of Dr. Lobo and Dr. Spergel. Specifically, the Chief Special Master noted that both Dr. Lobo and Dr. Spergel's reports indicated that S.K. could not exhibit an allergic reaction to the antigenic components of a vaccine she had not previously encountered, because a prior exposure is required to generate the antibodies that cause an allergic reaction upon a subsequent exposure. *Id.* at 9-10, 11. The Chief Special Master further discussed that both Dr. Lobo and Dr. Spergel raised issues concerning the reliability of Dr. Jorgensen's allergy testing results. Dr. Lobo opined S.K.'s skin testing results were not interpreted in a manner consistent with diagnostic protocol. *Id.* at 10. Dr. Spergel explained individuals with atopic dermatitis experience higher rates of sensitizations and other immune-mediated inflammatory diseases. *Id.* at 12. Given this predisposition, as well as S.K.'s erythematous reaction to the saline control, and the fact S.K. experienced an erythematous as opposed to the anaphylactic response to the vaccine itself, Dr. Spergel opined S.K.'s skin prick test results most likely evidenced an irritant reaction as opposed to a true positive allergic reaction. *Id.* at 12-13.

Weighing all the evidence, ultimately, the Chief Special Master found Dr. Jorgensen's conclusion unpersuasive, explaining:

At best, Petitioner can point to the skin-prick testing performed by Dr. Jorgensen in the winter of 2014 as supporting the conclusion that S.K. was allergic to either the antigenic components of these two vaccines or their ingredients. Ex. 4 at 20, 25, 29. However [], S.K. could *not* have been predisposed to a response to these vaccines (whether antigenically-specific or to other components) before first receiving them in September [2013], and because she unquestionably was displaying symptoms of atopic dermatitis by this time, any post-vaccination reaction is equally if not more likely attributable to the general sensitivity a person with atopic dermatitis would display to any stimuli. Fleischer at 581; *see* Weidinger at 1110. In addition, Drs. Lobo and Spergel raised reasonable points about the reliability of Dr. Jorgensen's testing results, and they persuasively noted that there is no evidence in this case that S.K. did possess an allergy to latex or yeast. Dr. Lobo Rep. at 6; Spergel Rep. at 3; *see* Ex. 4 at 20, 25, 29 (discussing skin prick tests against IPV and DTaP generally, but also showing a failure to test against yeast and latex).

Id. at 31.

Thus, the Court holds that the opinions of Dr. Lobo and Dr. Spergel provide evidentiary support for the Chief Special Master's findings in this case, including his determination not to credit Dr. Jorgensen's medical conclusions.⁶ It is clear that the Chief Special Master thoroughly

⁶ In a footnote, Petitioner argues that the treating physician records should negate the experts' testimony relying on *Capizzano*, 440 F.3d at 1324. However, "there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct – that it must be accepted in its

evaluated and weighed the evidence of record submitted, but was not persuaded by Petitioner's evidence in light of the greater weight of contrary evidence. Therefore, the Court holds that the Chief Special Master did not commit legal error, nor was his decision arbitrary or capricious.⁷

2. The Special Master Did Not Err In His Determination That Petitioner Did Not Meet Her Burden of Proof Under *Althen* Prong I

In her second objection, Petitioner challenges the factual determination by the Chief Special Master that the epidemiological study involving 2184 children aged 1-2—the Grüber study—provided by the Respondent was persuasive. Instead, Petitioner argues that: “Despite [...] S.K.’s compelling evidence presented in the form[] of testing, letters, experts’ opinions, and photographs of the damage done to her, the Special Master, for unknown reasons, gave that piece of ‘paper’ [the Grüber study] substantial weight. . . .” ECF No. 57 at 13. Moreover, Petitioner argues that her experts provided a plausible theory. By not accepting her theory, Petitioner asserts that the “Chief Special Master expects her to prove the specific biological mechanism of injury well beyond legal probability.” *Id.* at 17.

In her reply brief, Petitioner directs this Court’s attention to *Andreu* and its holding that “[w]hile considerable deference must be accorded to the credibility determinations of special masters, this does not mean that a special master can cloak the application of an erroneous legal stand in the guise of a credibility determination, and thereby shield it from appellate review.” ECF No. 62 at 4 citing *Andreu*, 569 F.3d at 1379. According to Petitioner, “the Chief Special Master cloaked his inappropriately high burden of proof and refusal to accept the mechanism of injury in a credibility determination.” ECF No. 62 at 5-6. “This warrants reversal.” *Id.* at 6. In support, Petitioner argues that she has produced a well-qualified expert immunologist (Dr. Axelrod), a well-qualified expert dermatologist (Dr. Wikas), and a well-qualified treating physician (Dr Jorgensen). *Id* at 4. Petitioner further points out that Respondent did not produce an expert in dermatology and argues that Respondent did not counter Dr. Wikas’s testimony. *Id.* at 4-5. Nor, argues the Petitioner, does the Chief Special Master discuss “why Dr. Axelrod or Dr. Wikas were less ‘credible.’” *Id.* at 5. And finally, Petitioner complains that because the case did not go to a live hearing, the credibility determination seemed to have “boiled down to the CV’s and expert reports.” *Id.* at 4.

The Court turns to the last argument first and notes that it was Petitioner who requested the matter be decided on the papers. Thus, the Court is confused when she complains that the credibility determination turned on the CV’s and expert reports. Of course, that was what was before the Chief Special Master and that is what he reviewed. When a case is submitted on the papers, that is exactly what a court turns to in order to decide a case. However, the Chief Special Master did not only look at the CV’s and expert reports. In his decision, the Chief Special Master acknowledged Petitioner’s literature as well. Indeed, in his decision he writes:

entirety and cannot be rebutted.” *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 745-746 n.67. The Chief Special Master was under no legal obligation to credit Dr. Jorgensen’s findings, and his decision not to credit those findings is supported by evidence in the record.

⁷ The Chief Special Master also articulated alternative causation findings, i.e. breastfeeding, but the Court need not address this issue in light of its analysis.

I find that preponderant evidence (particularly some of the literature filed in this case) supports the conclusion that exposure to potentially allergenic vaccine components could trigger the kind of immunologic reaction necessary to produce an IgE-mediated allergic reaction . . . But this alone is insufficient to support finding that vaccines can also cause atopic dermatitis—a condition that much of the literature distinguishes from a true allergic reaction. . . [and that] there exists merely a handful of studies—some of which *do* find a causal relationship between vaccines and atopic dermatitis . . .”

Dec. at 26-27. Thus, it is clear that the Chief Special Master also reviewed the literature and medical studies that were filed by the parties.

Here, the Chief Special Master’s finding that Petitioner failed to meet her burden on causation turned in large part on his assessment of the witnesses’ respective credibility. Contrary to Petitioner’s argument that the Chief Special Master did not explain why her witnesses were less credible, his decision explained this determination. For instance, with regard to Dr. Wikas he wrote:

Relying on Dr. Axelrod’s report and the accompanying literature, Dr. Wikas attributed S.K.’s atopic dermatitis exacerbation to an allergic reaction to the latex and yeast components of the vaccines she received in September 2013. Wikas Rep. at 6. He did not address the absence of record evidence that S.K. had ever *previously* experienced latex and yeast allergies, however. He otherwise noted the temporal relationship between S.K.’s atopic dermatitis flare and the receipt of her September 18, 2013 which he considered direct evidence of a causal association.

Id. at 8-9. Then, in a footnote, the Chief Special Master noted that:

Despite Dr. Wikas being board certified in dermatology, most of Dr. Wikas’ report mimics that of Dr. Axelrod—an immunologist—and it is also evident that Dr. Wikas relied heavily if not exclusively on the literature previously submitted by Dr. Axelrod. *See generally* Axelrod Rep.; Wikas Rep.

Id. at 8 fn. 13. With regard to Dr. Axelrod, the Chief Special Master wrote:

While the general proposition that vaccines can cause an allergic reaction in the recipient is supported by the literature supplied in this case in connection with Dr. Axelrod’s report, those same articles emphasize the importance of distinguishing between *true* allergic reactions to specific components of a vaccine versus a reaction that is merely temporally related or mediated by a non-immunological mechanism. *See* Zudaire at 308, 311–312 (noting that delayed reactions should not be diagnosed as vaccine allergies and providing examples of reactions that can simulate allergic reactions). One possible reaction that may be mischaracterized as a vaccine allergy is the appearance of a rash, which may

actually correspond to the exacerbation of a preexisting condition such as atopic dermatitis. *Id.* at 312. Notably, however, neither Zudaire or Dr. Axelrod explain how the *first* exposure to a particular vaccine can exacerbate preexisting atopic dermatitis.

Id. at 7.

Noting that Dr. Spergel was not board-certified in dermatology, the Chief Special Master noted however that Dr. Spergel had “significant experience studying atopic dermatitis and other immunologically-mediated dermatological disorders, and he has served on several committees dedicated to atopic dermatitis and eczema.” *Id.* at 12. He also noted that Dr. Spergel had also published numerous articles and presented on the topics of allergy, immunology, and atopic dermatitis. *Id.* He further noted Dr. Spergel’s conclusion:

Thus, according to Dr. Spergel, there was no evidence that S.K. ever suffered from allergies to either latex or yeast, and her development and subsequent exacerbation of atopic dermatitis cannot be attributed to an allergic reaction to those kinds of components. In furtherance of that opinion, Dr. Spergel pointed out that even if S.K. did have an allergy to the vaccines she received on September 18, 2013, she could not have experienced any reaction within minutes of vaccine administration because she had not been previously exposed to the vaccines, and she could not have developed sensitization to them.

Id. (internal citations omitted).

Thus, after weighing this evidence, the Chief Special Master was able to conclude:

Petitioner’s experts failed to provide adequate support for the proposed theory. Though qualified to offer an opinion in the matter, Drs. Axelrod and Wikas were less credible overall in the opinions they offered when compared to Respondent’s expert, Dr. Spergel.

Id. at 32-33. The Chief Special Master fully weighed each of the experts’ testimony and his finding that Petitioner’s experts were less credible in their opinions concerning causation is supported by the record.

Furthermore, merely positing a possible or plausible theory is insufficient to satisfy a petitioner’s burden under *Althen* prong I. *Boatmon*, 941 F.3d at 1360 (holding special master erred in allowing a theory that was at best “plausible” to satisfy petitioner’s burden of proof). Although a Vaccine Act claimant is not required to present proof of causation to the level of scientific certainty, the special master is entitled to require some indicia of reliability to support the assertion of the expert witness. *Daubert* is not required, but reliability and reputability are. *Id.* at 1360 (internal citations omitted).

In this case, Respondent offered an epidemiological study as well. Although, as noted by the Chief Special Master, a Petitioner is not required to offer epidemiological studies; a Special

Master may, however, consider studies presented that bear on a claim and afford them evidentiary weight. Dec. at 29; *see also, Andreu*, 569 F.3d at 1379. Here, the Chief Special Master weighed the Grüber study against evidence presented by Petitioner and determined that the Grüber study was “very persuasive” and “worthy of substantial weight.” Dec. at 27. In coming to this conclusion, the Chief Special Master noted that: (1) the Grüber study involved over two thousand children, (2) the study focused on children who were at high risk of developing atopic dermatitis, or who already suffered from it, and (3) the study “dealt specifically with the propensity of vaccines to cause or exacerbate atopic dermatitis” – issues the chief special master observed “go[] directly to [petitioner’s] central contentions in this case.” *Id.* at 27, 29. Thus, in support of these findings, the Chief Special Master explicitly gave the reasons for his reliance on the Grüber study, rather than the literature and medical studies provided the Petitioner.

And finally, the Chief Special Master did not apply a heightened burden to her claim. The Chief Special Master thoroughly evaluated the evidence of record, including Drs. Axelrod and Wikas opinions regarding vaccine causation, and found that Petitioner failed to show that the vaccines S.K. received more likely than not caused her injury.

Again, as this Court ought not to second-guess the Special Master’s fact-intensive conclusions, particularly in cases “in which the medical evidence of causation is in dispute,” *Hodges*, 9 F.3d at 961, the Court will not do so here. The Federal Circuit has “unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act.” *Porter*, 663 F.3d at 1250. The relevant inquiry for this Court is whether the special master weighed the evidence in the record and explained why he assigned more weight to some evidence rather than to other evidence. And that is exactly what the Chief Special Master did; and he concluded that Dr. Spergel was more persuasive than Drs. Axelrod and Wikas. This conclusion was supported by evidence and therefore not improper.

3. The Decision That Six Days Was Not An Appropriate Framework Was Not Error

In her third argument, petitioner again challenges the Chief Special Master’s weighing of the evidence. Petitioner asserts: “Chief Special Master Corcoran’s analysis directly contradicts the expert testimony of Petitioner’s immunologist, Dr. Axelrod,” who “clearly explained the appropriateness of timing in S.K.’s case. . . . Therefore, the Special Master erred in holding that this timeframe was too long” ECF No. 57 at 18.

However, the Chief Special Master explained in detail the evidence he relied on in rejecting Dr. Axelrod’s conclusion that six days was a medically reasonable timeframe for S.K.’s onset of symptoms following her Hepatitis B vaccination. In his Decision, the Chief Special Master first noted, “Respondent’s experts, along with much of the literature submitted in this matter, proposed that the onset of delayed allergic reactions will occur *at least* within forty-eight hours of allergen exposure, peaking three to four days post-exposure.” Dec. at 27-28 (*citing* Chung at 51; Wood at 521-22). He then reasoned that S.K.’s onset approximately six days following exposure “is inconsistent with the most scientifically reliable/medically acceptable

timeframe.” *Id.* at 28. The Chief Special Master further explained that one of the articles Dr. Axelrod submitted to support his opinion that adaptive immune responses to an allergen can occur for up to twenty-five days, did not appear to actually support that position. *Id.* Thus, it is clear, that the Chief Special Master’s finding is supported by evidence in the record; therefore, it will not be disturbed.

4. The Chief Special Master’s Determination That Petitioner Did Not Satisfy Her Burden Under *Loving* Is Supported By Evidence In The Record, Therefore, The Determination Was Neither Arbitrary Nor Capricious.

It is true, as Petitioner asserts, that she produced literature that supports the conclusion that the IPV and DTaP vaccines could, at least transiently, aggravate existing atopic dermatitis. *Id.* at 29. However, the Chief Special Master found the Grüber study persuasive evidence in opposition to this contention. *Id.* He further found that Respondent “offered credible and persuasive testimony that (coupled with the filed literature) substantially detracted from Petitioner’s proffered theory.” *Id.* at 30. The Chief Special Master also found that Respondent’s experts “raised reasonable points about the reliability of Dr. Jorgensen’s testing results” finding that he did not find Dr. Jorgensen’s conclusions persuasive. *Id.* at 31. And he explained that he found respondent’s expert, Dr. Spergel, more credible than petitioner’s experts. *Id.* at 32-33. Therefore, the Court holds that the Chief Special Master’s findings are grounded in the record, and thus not arbitrary or capricious.

IV. Conclusion

Petitioner has failed to point to any other evidence in the record to show that the findings were not substantiated by the record. As long as the special master’s findings of fact are “based on evidence in the record that [is] not wholly implausible, [this Court is] compelled to uphold that finding as not being arbitrary or capricious.” *Cedillo*, 617 F.3d at 1338. By her own arguments, Petitioner essentially concedes that the Chief Special Master weighed the evidence in the record. Petitioner does not contend his findings are wholly without evidentiary support. Rather, she maintains respondent’s evidence was afforded too much weight, and Petitioner’s evidence too little. The relevant inquiry, however, is whether the Chief Special Master’s factual determinations are based on evidence in the record. The Court holds that the Decision itself reflects that they are.

For the reasons stated above, the court **DENIES** Petitioner’s motion for review and **SUSTAINS** the decision of the Chief Special Master. The Clerk is directed to enter judgment accordingly.

In addition, pursuant to Vaccine Rule 18(b), the parties shall review this decision and submit any proposed redactions, by providing the Court with redlined pages showing the redactions, **within 14 days from the date of this Opinion and Order.**

IT IS SO ORDERED.

s/Edward J. Damich
EDWARD J. DAMICH
Senior Judge